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220CT98 E399075-1 D01030
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1.	Your Reference	KC/PU3556
2.	Patent application number *(The Patent office will fill in this part)*	22 OCT 1998 **9823036.0**
3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	GLAXO GROUP LIMITED GLAXO WELLCOME HOUSE BERKELEY AVENUE GREENFORD MIDDLESEX UB6 0NN
	Patents ADP number *(if you know it)*	03557003
	If the applicant is a corporate body, give the country/state of its corporation	
4	Title of the invention	FLUTICASONE LOTION HAVING IMPROVED VASOCONSTRICTOR ACTIVITY
5	Name of your agent *(if you know one)*	KAREN CRAWLEY (SEE CONTINUATION SHEET)
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	GLAXO WELLCOME PLC GLAXO WELLCOME HOUSE, BERKELEY AVENUE GREENFORD, MIDDLESEX UB6 ONN, GB
	Patents ADP number *(if you know it)*	7259069001

6. If you are declaring priority from one or more earlier patent applications, give the country and date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country	Priority application number *(if you know it)*	Date of Filing (day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)

8.	Is a statement of inventorship and of right to grant a patent required in support of this request? *(Answer yes if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body.* *See note (d))*	YES

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Continuation sheets of this form	1
Description	13
Claim(s)	3
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10. If you are also filing any of the following, state how many against each item

Priority Documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patent Form 9/77)*	
Request for substantive examination *(Patent Form 10/77)*	
Any other documents *(please specify)*	

11. **I/We request the grant of a patent on the basis of this application**

Signature: Karen Crawley **21 October 1998**

AGENT FOR THE APPLICANTS

12. Name and daytime telephone number of person to contact in the United Kingdom

Kim Allen

0181-966 5721

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(See Page 1 No. 5)

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FLUTICASONE LOTION HAVING IMPROVED VASOCONSTRICTOR ACTIVITY

Background of the Invention

Field of the Invention

The present invention is directed to a fluticasone lotion having improved vasoconstrictor activity over a cream formulation. The fluticasone lotion exhibits significant vasoconstrictor potency and excellent anti-inflammatory activity.

Description of Related Art

Fluticasone propionate is a steriod having anti-inflammatory, anti-pruitic, and vasoconstrictive properties.

Fluticasone propionate cream (0.05%) is sold under the tradename Cutivate® cream. Each gram of Cutivate® cream (0.05%) contains 0.5 mg fluticasone propionate in a base of propylene glycol, mineral oil, cetostearyl alcohol, ceteth-20, isopropyl myristate, buffers and preservatives.

Mineral oil is a known occlusive agent. Occlusion in topical drug delivery is known to increase the vasoconstrictor potency of the topical steroid. By increasing the vasoconstrictor potency, the effectiveness of the steroid is increased. Disadvantageously, occlusive agents such as mineral oil can reduce the esthetic appeal of topical formulations as they may impart an undesirable oily feel to the skin. With the removal or significant reduction of the occlusive agent, one of ordinary skill in the art would expect to see a decrease in the vasoconstrictor potency of the steroid, and thus a decrease in the effectiveness of the topical steroid formulation.

Surprisingly, it has been found by the present inventors that the removal of the occlusive agent actually increases the vasoconstrictor potency of fluticasone, and thus, the effectiveness of the steroid. Moreover, a lotion greatly improves the organoleptic feel and spreadability of the drug over a large area, when compared with a cream. The present invention is based on the above finding.

Summary of the Invention

The present invention is directed to a topical fluticasone lotion for the treatment of dermatological disorders. The lotion comprises:

(a) about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;

(b) about 1.0 to about 10.0 wt.% of a C_{14}-C_{20} fatty alcohol, or mixtures thereof;

(c) about 1.0 to about 5.0 wt.% of at least one skin conditioning agent; and

(d) about 5.0 to about 15.0 wt.% of propylene glycol; and up to about 10.0 wt.% mineral oil or soft white paraffin, and the balance being water which can contain additives such as preservatives and buffers.

This invention is also directed to a topical fluticasone lotion which comprises:

(a) fluticasone propionate in an amount of from about 0.005 to about 1.0 wt.%;

(b) a C_{14}- C_{20} fatty alcohol, or mixtures thereof, in an amount of from about 3.0 to about 7.0 wt.%;

(c) at least one skin conditioning agent in an amount of from about 0.5 to about 3.0 wt.%;

(d) a surfactant in an amount of about 0.25 to about 3.0 wt.%;

(e) propylene glycol in an amount of from about 7.0 to 12.0 wt.%; and

(f) up to about 10 wt.% mineral oil or soft white paraffin.

Detailed Description of the Preferred Embodiments

The lotion of the present invention has the added benefit of being chemically and physically stable for at least 6 months at 40°C.

Fluticasone or a pharmaceutically acceptable salt or ester thereof, such as fluticasone proprionate is added to the formulation in an amount of from about 0.005 to about 1.0 wt.% preferably 0.005 to 0.5 wt.%, and most preferably about 0.005 to about 0.1 wt.%.

The C_{14}-C_{20} fatty alcohol or mixtures thereof are added to the formulation as a thickener and stabilizer. Examples include, but are not limited to, cetyl alcohol, stearyl alcohol, and cetostearyl alcohol. The C_{14}-C_{20} fatty alcohol is present in an amount of

from about 1.0 to about 10.0 wt.%, preferably about 3.0 to about 7.0 wt.%, and most preferably about 4.0 to about 6.0 wt.%.

Conventional skin conditioning agents known in the art such as emollient skin conditioning agents can be used in preparing the lotion of the present invention. Skin conditioning agents are defined in the CTFA (Cosmetic Toiletry and Fragrance Association) Cosmetic Ingredient Handbook (2nd ed. 1992) and the Handbook of Pharmaceutical Excipients (2nd ed. 1994). Examples of such skin conditioning agents include, but are not limited to cholesterol, glycerine, glycerol monostearate, isopropyl myristate and palmitate, and lanolin alcohols, or mixtures thereof. Particular examples are isopropyl myristate and cetostearyl alcohol. The skin conditioning agent is added in an amount of from about 1.0 to about 5.0 wt.%, preferably about 1.0 to about 3.0 wt.%, and most preferably about 1.0 to about 2.0 wt.%. In a preferred embodiment, dimethicone is combined with at least one other skin conditioning agent, where the amount of dimethicone present is the formulation up to about 5.0 wt.%, preferably about 0.5 to about 3.0 wt.% and most preferably about 1.0 to about 2.0 wt.% of the formulation.

Conventional surfactants used in the art of topical formulations for forming an oil-in-water emulsion can be used and are not limited. Examples of such surfactants are polyoxyalkene oxides of C_{14}-C_{20} fatty alcohols and polyoxyalkylene sorbitan esters, or mixtures thereof with particular examples being Cetomacrogol® 1000 (Crodor Inc.), Ceteth-20®, Tween® 40 or Brig® 78. The surfactant is added in an amount of about 0.25 to about 3.0 wt.%, preferably about 0.5 to about 2.0 wt.%, and most preferably about 0.75 to about 1.5 wt.%.

Mineral oil or white soft paraffin can be added to the lotion in small amounts to act as a skin conditioner. The lotion may contain no mineral oil or no white soft paraffin at all (0 wt.%) or up to about 10.0 wt.%, particularly up to about 5.0 wt.% and most preferably up to about 2.0 wt.%.

Propylene glycol is added to the lotion formulation in an amount of from about 5.0 to about 15.0 wt.%, preferably about 7.0 to about 12.0 wt.% and most preferably 9.0 to 11.0 wt.%.

The viscosity of the topical lotion is from about 2,000 to about 17,000 cps, preferably about 3,000 to about 13,000 cps, as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C.

The pH range of the topical lotion should be from about 4 to 7. Preferred buffers to achieve this range, include, but are not limited to sodium citrate/citric acid, dibasic sodium phosphate/citric acid, and the like.

Preservatives used in the present invention can be any of those conventionally used in the art of topical formulations and preferably the formulation should pass US Pharmacopoeia, British Pharmacopoeia and European Pharmacopoeia standards. Preferred preservatives include, but are not limited to imidurea, methylparaben, propylparaben and the like.

Treatment with the lotion of the present invention is accomplished by applying the lotion to the affected areas to be treated. The treatment regimen is varied from patient to patient and condition to be treated and is usually applied once to twice a day. The lotion of the present invention is used to treat inflammatory and pruritic manifestations of corticosteriod-responsive dermatoses.

The lotion of the present invention is manufactured in a conventional manner by mixing the ingredients at elevated temperatures (such as from 45-80°C) then cooling in order to achieve a smooth, homogeneous oil-in-water emulsion.

The following examples merely illustrate the lotion compositions of the invention and not to be construed as limiting. All weight percentages are weight percentages based on the total weight of the composition.

Examples

Example 1

A topical 0.05 wt.% fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Cetostearyl alcohol, NF	5.00

Isopropyl myristate, NF	1.00
Dimethicone 360, NF	1.00
Cetomacrogol 1000, BP	1.00
Propylene glycol, USP	10.00
Imidurea, NF	0.30
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Citric acid (anhydrous), USP	.05
Sodium citrate, USP	0.08
Purified water, USP	s

Example 2

A topical 0.05 wt.% fluticasone propionate lotion formulation in accordance with the present invention is prepared having the following composition:

	(w/w)
Cetostearyl alcohol, NF	5.25
Isopropyl myristate, NF	2.00
Propylene glycol, USP	0.00
Ceteth-20	0.75
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Citric Acid (anhydrous)	0.05
Dibasic sodium phosphate	0.06
Purified water, USP	qs

Example 3

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	5.0
Mineral Oil	3.0

Isopropyl myristate	3.0
Ceteth-20	0.75
Propylene Glycol	0.0
Citric Acid (anhydrous)	0.05
Dibasic Sodium Phosphate	0.06
Imidurea	0.20
Water	qs

Example 4

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	5.25
Mineral Oil	1.0
Isopropyl myristate	1.0
Ceteth-20	0.75
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Dibasic Sodium Phosphate	0.06
Imidurea	0.20
Water	qs

Example 5

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	5.0
Mineral Oil	10.0
Isopropyl myristate	5.0
Ceteth-20	0.75
Propylene Glycol	10.0

Citric Acid (anhydrous)	0.05
Dibasic Sodium Phosphate	0.06
Imidurea	0.20
Water	qs

Example 6

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	7.0
Isopropyl myristate	2.5
Dimethicone	2.5
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Sodium Citrate	0.075
Imidurea	0.30
Water	qs

Example 7

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	7.0
Isopropyl myristate	5.0
Dimethicone	2.5
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Sodium Citrate	0.075

Imidurea	0.30
Water	qs

Example 8

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	6.0
Isopropyl myristate	2.0
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Sodium Citrate	0.075
Imidurea	0.30
Water	qs

Example 9

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	4.7
Isopropyl myristate	3.75
Dimethicone	3.75
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Sodium Citrate	0.075
Imidurea	0.30
Water	qs

Example 10

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.05
Cetosteoryl Alcohol	2.4
Isopropyl myristate	2.5
Dimethicone	5.0
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Citric Acid (anhydrous)	0.05
Sodium Citrate	0.075
Imidurea	0.30
Water	qs

Example 11

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.01
Stearyl Alcohol	5.0
Isopropyl myristate	3.0
Dimethicone	3.0
Ceteth-20	0.75
Propylene Glycol	5.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 12

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	.01
Stearyl Alcohol	2.5
Mineral Oil	1.0
Isopropyl myristate	1.0
Dimethicone	1.0
Cetomacrogol 1000	0.5
Propylene Glycol	15.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 13

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.1
Cetyl Alcohol	7.0
Mineral Oil	2.0
Isopropyl myristate	2.0
Dimethicone	2.0
Cetomacrogol 1000	1.5
Propylene Glycol	10.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 14

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.1
Stearyl Alcohol	7.0
Mineral Oil	2.5
Dimethicone	2.5
Ceteth-20	1.0
Propylene Glycol	15.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 15

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.1
Cetostearyl Alcohol	5.0
Mineral Oil	2.5
Dimethicone	1.0
Tween®40	0.5
Propylene Glycol	10.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 16

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.1
Stearyl Alcohol	5.25

Mineral Oil	5.0
Brig®78	2.0
Propylene Glycol	5.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 17

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.05
Cetyl Alcohol	2.0
Isopropyl myristate	5.0
Cetomacrogol 1000	0.5
Propylene Glycol	10.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Example 18

A topical fluticasone propionate lotion in accordance with the present invention is prepared having the following composition:

	(w/w)
Fluticasone Propionate	0.05
Cetyl Alcohol	2.5
Dimethicone	5.0
Cetomacrogol 1000	1.0
Propylene Glycol	10.0
Imidurea, NF	0.20
Methyl paraben, USP	0.20
Propyl paraben, USP	0.10
Water	qs

Experimental Method
Vasoconstriction Study

The topical anti-flammatory activity of fluticasone propionate formulations was measured using a vasoconstriction assay (McKenzie and Stoughton, Arch. Dermatol., 86, 608(1962)).

Approximately 0.1 mL of the drug product was placed on a 2 cm^2 area of the volar aspect of each volunteer's forearm. Application sites were protected with a guard to prevent removal or smearing, but were not occluded. After approximately 16 hours of contact, the protective guards were removed and the sites gently washed and dried. Skin vasoconstrictor evaluations were preformed on a 4 point scale (0 [no blanching]-3[marked blanching]) at time points corresponding to 2, 3, 6, 8, and 24 hours after drug removal. The data from this clinical trial were used to calculate the mean blanching response and the area under the curve (AUC) for the blanching Versus time.

The higher the score, mean or area under the curve (AUC), the more topically potent:

Measure*	Lotion Example 1	Lotion Example 2	Cutivate® (Fluticasone proprionate) Cream Comparative Example
AUC	28.4	26.7	21.4
Mean	1.58	1.49	1.22

*Results from 17 volunteers.

The inventive lotions show higher vasoconstriction scores than fluticasone Cream. By looking at the 17 patient data set, the vasoconstriction potency of the inventive lotions over the cream is greater.

It will be apparent to those skilled in the art that many modifications thereof may be made without departing from the spirit and scope of the invention.

We claim:

1. A topical lotion which comprises:

(a) about 0.005 to about 1.0 wt.% fluticasone, or a pharmaceutically acceptable salt or ester thereof;

(b) about 1.0 to about 10.0 wt.% of a C_{14}-C_{20} fatty alcohol or mixtures thereof;

(c) about 1.0 to about 5.0 wt.% of one or more skin conditioning agents;

(d) about 5.0 to about 15.0 wt.% of propylene glycol; and

(e) up to about 10.0 wt.% of mineral oil or white soft paraffin.

2. A topical fluticasone lotion which comprises:

(a) fluticasone propionate in an amount of from about 0.005 to about 1.0 wt.%;

(b) a C_{14}-C_{20} fatty alcohol, or mixtures thereof, in an amount of from about 3.0 to about 7.0 wt.%;

(c) one or more skin conditioning agents in an amount of from about 0.5 to about 3.0 wt.%;

(d) a surfactant in an amount of about 0.25 to about 2.0 wt.%;

(e) propylene glycol in an amount of from about 7.0 to about 12.0 wt.%; and

(f) up to about 10 wt.% of mineral oil or white soft paraffin.

3. The lotion according to claim 1, further comprising up to about 5.0 wt.% dimethicone.

4. The lotion according to claim 2, further comprising up to about 5.0 wt.% dimethicone.

5. The lotion according to claim 1, wherein said pharmaceutically acceptable salt of fluticasone is fluticasone propionate.

6. The lotion according to claim 1, having the formula:

Fluticasone propionate	0.05 wt.%
Cetostearyl alcohol	5.00 wt.%
Isopropyl myristate	1.00 wt.%
Dimethicone 360	1.00 wt.%
Cetomacrogol 1000	1.00 wt.%
Propylene glycol	10.00 wt.%

Imidurea	up to	0.30 wt.%
Methyl paraben	up to	0.20 wt.%
Propyl paraben	up to	0.10 wt.%
Citric acid (anhydrous)		0.05 wt.%
Sodium citrate		0.08 wt.%
Purified water		qs

7. The lotion according to claim 1, having the formula

Fluticasone propionate	0.05 wt.%
Cetostearyl alcohol	5.25 wt.%
Isopropyl myristate	2.00 wt.%
Propylene glycol	10.00 wt.%
Imidurea	0.20 wt.%
Methyl paraben	0.20 wt.%
Propyl paraben	0.10 wt.%
Purified water	qs

8. The lotion according to claim 1, having a viscosity of from about 2,000 to about 17,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C.

9. The lotion according to claim 2, having the formula

Cetostearyl alcohol	5.25 wt.%
Isopropyl myristate	2.00 wt.%
Propylene glycol	10.00 wt.%
Imidurea	0.20 wt.%
Methyl paraben	0.20 wt.%
Propyl paraben	0.10 wt.%
Purified water	qs

10. The lotion according to claim 1, having a viscosity of from about 3,000 to about 13,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C

11. The lotion according to claim 2, having a viscosity of from about 3,000 to about 13,000 cps as measured by a Brookfield viscometer fitted with a #27 spindle at 10 rpm at 25°C.

12. The lotion according to claim 1, containing no mineral oil or white soft paraffin.

13. The lotion according to claim 2, containing no mineral oil or white soft paraffin.

14. A method of increasing the vasoconstrictor potency of fluticasone which comprises applying to the skin the lotion according to claim 1.

15. A method of increasing the vasoconstrictor potency of fluticasone proprionate which comprises applying to the skin the lotion according to claim 2.

16. Use of the lotion according to claim 1 to increase the vasoconstrictor potency of fluticasone.

17. Use of the lotion according to claim 2 to increase the vasoconstrictor potency of fluticasone proprionate.

18. A process for preparing a lotion according to claim 1, which comprises mixing the ingredients recited in claim 1 at elevated temperature; and then cooking said mixture.

19. A process for preparing a lotion according to claim 1, which comprises mixing the ingredients recited in claim 1 at elevated temperature; and then cooking said mixture.

ABSTRACT OF THE DISCLOSURE

The present invention is directed to a fluticasone lotion having improved vasoconstrictor activity. The fluticasone lotion exhibits high vasoconstrictor potency and excellent anti-inflammatory activity.

PG Co 9903[illegible]2
Glaxo Wellcome Plc
27 1099